IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC. and PFIZER LIMITED,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. _____
	)	
UMEDICA LABORATORIES PVT., LTD.,	)	
	)	
Defendant.	)	

COMPLAINT

Pfizer Inc. and Pfizer Limited (collectively "Plaintiffs" or "Pfizer"), by their attorneys, for their Complaint against Umedica Laboratories Pvt., Ltd. ("Defendant" or "Umedica") allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Umedica for infringement of United States Patent No. 6,469,012 (the "'012 patent").

2. This action arises out of Umedica's filing of Abbreviated New Drug Application ("ANDA") No. 209302 seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's revolutionary oral treatment for erectile dysfunction, Viagra®, prior to the expiration of the '012 patent.

THE PARTIES

3. Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 235 East 42nd Street, New York, New York 10017. Pfizer invests extensively in designing, developing, and evaluating new and innovative pharmaceutical products and sells pharmaceutical products to the public throughout the United States.

4. Pfizer Limited is a corporation organized under the laws of England and has its principal place of business at Ramsgate Road, Sandwich, Kent, England.

5. Pfizer has all right, title, and interest in the '012 patent and the right to sue for infringement thereof.

6. On information and belief, defendant Umedica is a corporation organized and existing under the laws of India, having its principal place of business at 105/108 Rewa Chambers., 1st Floor, 31, New Marine Lines, Mumbai 400020, India.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. This Court has personal jurisdiction over Umedica by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including in the State of Delaware. In particular, this action arises out of Umedica's filing of ANDA No. 209302 seeking approval by the FDA to sell, prior to the expiration of the '012 patent, 50 mg and 100 mg tablets of sildenafil citrate for treatment of erectile dysfunction (the "Umedica Generic Tablets"), throughout the United States, including in the State of Delaware.

9. On information and belief, if ANDA No. 209302 is approved, Umedica Generic Tablets will, among other things, be marketed and distributed in the State of Delaware, prescribed by physicians practicing in the State of Delaware, dispensed by pharmacies located within the State of Delaware, and/or used by patients in the State of Delaware.

10. Umedica's infringing activities with respect to its filing of ANDA No. 209302 and its intent to commercialize and sell Umedica Generic Tablets has led and/or will lead to

foreseeable harm and injury to Plaintiffs, including Pfizer Inc., which is incorporated in Delaware.

11. In the alternative, this Court has jurisdiction over Umedica under Federal Rule of Civil Procedure 4(k)(2). Umedica has contacts with the United States by, *inter alia*, having filed its ANDA with the FDA.

12. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

13. Venue is proper in this judicial district because defendant Umedica is a corporation organized and existing under the laws of India and has its principal place of business in India.

BACKGROUND

The ’012 Patent

14. On October 22, 2002, the United States Patent and Trademark Office (“USPTO”) issued the ’012 patent, titled “Pyrazolopyrimidinones for the Treatment of Impotence,” based on an application filed by Dr. Peter Ellis and Dr. Nicholas Kenneth Terrett. Drs. Ellis and Terrett duly and legally assigned the ’012 patent to Pfizer Inc. The USPTO, during the course of reexamination proceedings, confirmed the patentability of claims 1–23, 25, and 26 of the ’012 patent over numerous prior art references. The USPTO found claim 24 not patentable. Pfizer is only asserting claims 25 and 26 of the ’012 patent in this case. In *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 803 F. Supp. 2d 409 (E.D. Va. 2011), the Eastern District of Virginia found claims 25 and 26 of the ’012 patent valid, enforceable, and infringed. A copy of the ’012 patent is attached hereto as Exhibit A.

15. Pfizer Limited has the right to grant licenses and enforce the ’012 patent.

Orange Book Listing for Viagra

16. Pfizer holds approved New Drug Application No. 020895 for treating erectile dysfunction with sildenafil citrate which Pfizer sells under the registered name Viagra. Treatment of erectile dysfunction with Viagra is covered by the ’012 patent. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the ’012 patent is listed in the FDA publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) as covering Viagra.

17. The Orange Book lists the ’012 patent’s expiration date as October 22, 2019. The Orange Book further reflects that Viagra has been granted pediatric exclusivity through April 22, 2020.

Umedica’s ANDA

18. By letter dated October 10, 2017, (the “Umedica Notice Letter”) and received by Pfizer on October 11, 2017, Umedica notified Pfizer that it had filed ANDA No. 209302 with the FDA, seeking approval under the Federal Food, Drug, and Cosmetic Act to market and sell, prior to the expiration of the ’012 patent, 50 mg and 100 mg tablets of sildenafil citrate, generic copies of Viagra, for treatment of erectile dysfunction.

19. The Umedica Notice Letter asserts that ANDA No. 209302 contains a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the ’012 patent is “invalid and/or each valid claim[] of the ‘012 patent will not be infringed by the commercial manufacture, use, or sale of” of Umedica Generic Tablets.

20. Attached to the Umedica Notice Letter was Umedica’s Detailed Factual and Legal Basis for Umedica’s Paragraph IV Certification (“Umedica’s Detailed Statement”) asserting the purported factual and legal bases for Umedica’s contention that the ’012 patent is invalid and/or

each valid claim of the ’012 patent will not be infringed by the commercial manufacture, use, or sale of of Umedica Generic Tablets.

21. Umedica’s Detailed Statement does not contain a noninfringement argument with respect to any claim of the ’012 patent.

22. On information and belief, upon approval of ANDA No. 209302, Umedica will distribute the Umedica Generic Tablets throughout the United States, including throughout Delaware.

COUNT I
(Patent Infringement by Umedica)

23. The allegations of paragraphs 1-22 above are repeated and re-alleged as if set forth fully herein.

24. Pursuant to 35 U.S.C. § 271(e)(2)(A), Umedica’s filing of ANDA No. 209302 seeking approval to market Umedica Generic Tablets is an act of infringement of each of claims 25 and 26 of the ’012 patent, entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 209302 be a date which is not earlier than the expiration date of the ’012 patent.

25. Umedica had knowledge of the ’012 patent when it submitted ANDA No. 209302 to the FDA.

26. On information and belief, upon FDA approval, Umedica intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Umedica Generic Tablets with Umedica’s proposed labeling. The use of Umedica Generic Tablets in accordance with and as directed by Umedica’s proposed labeling would infringe claims 25 and 26 of the ’012 patent.

27. Upon information and belief, Umedica intends to actively induce infringement of each of claims 25 and 26 of the ’012 patent.

28. Upon information and belief, Umedica knows that Umedica Generic Tablets and the proposed labeling are especially made or adapted for use in infringing each of claims 25 and 26 of the ’012 patent and that the Umedica Generic Tablets and the proposed labeling are not suitable for any substantial noninfringing use.

29. Upon information and belief, Umedica intends to contribute to the infringement of each of claims 25 and 26 of the ’012 patent.

30. The foregoing actions by Umedica constitute and/or would constitute infringement of each of claims 25 and 26 of the ’012 patent, active inducement of infringement of each of claims 25 and 26 of the ’012 patent, and/or contribution to the infringement by others of each of claims 25 and 26 of the ’012 patent.

31. Pfizer will be substantially and irreparably harmed if Umedica is not enjoined from infringing the ’012 patent. Pfizer has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Umedica’s submission of ANDA No. 209302 was an act of infringement and that Umedica’s making, using, offering to sell, selling, or importing Umedica Generic Tablets prior to the expiration of the ’012 patent will infringe, actively induce infringement, and/or contribute to the infringement of the ’012 patent;

B. A judgment that the effective date of any FDA approval for Umedica to make, use, offer for sale, sell, market, distribute, or import the ANDA Products be no earlier than the expiration of the ’012 patent, or any later expiration of exclusivity to which Pfizer is entitled;

C. A permanent injunction enjoining Umedica, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, offering for sale, marketing, distributing, or importing the Umedica Generic

Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the '012 patent;

D. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Pfizer to an award of its reasonable attorneys' fees for bringing and prosecuting this action;

E. An award of Pfizer's costs and expenses in this action;

F. Such further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Aaron Stiefel
Daniel P. DiNapoli
Jeffrey Martin
Philip Smithback
Stephanie Piper
ARNOLD & PORTER KAYE SCHOLER LLP
250 West 55th Street
New York, NY 10019-9710
(212) 836-8000

Soumitra Deka
ARNOLD & PORTER KAYE SCHOLER LLP
Three Embarcadero Center
San Francisco, CA 94111-4024
(415) 471-3100

October 31, 2017